Updated Principles for Risk Analysis

Society of Toxicology
Risk Assessment Specialty Section Teleconference
November 14, 2007

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- Historical Perspective
- 2007 Updated Principles for Risk Analysis
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- Questions and Answers

Disclaimer: Opinions expressed are my own and do not necessarily represent the views of the Office of Management and Budget.

Historical Perspective (1)

- Paperwork Reduction Act (1995)
  - Requires OMB to “develop and oversee the implementation of policies, principles, standards, and guidelines to…apply to Federal agency dissemination of public information”
  - http://www.reginfo.gov/public/reginfo/pra.pdf

- Information Quality Law (2000)
  - Directed OMB to issue government-wide guidelines to Federal agencies for ensuring and maximizing the **Quality, Objectivity, Utility and Integrity** of information disseminated by Federal agencies.

- Information Quality Guidelines (2002)
  - Agencies must meet basic information quality standards.
  - The more important the information, the higher the standards.
  - http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

Historical Perspective (2)

- OMB Circular A-4 for Regulatory Review (2003)
  - Updated to provide guidance on regulatory analysis as it relates to risk management decisions, particularly those required under EO 12866.
  - http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf

- Information Quality Bulletin on Peer Review (2004)
  - Defines government-wide expectations for the peer review of significant scientific information.
  - Goal is to enhance the quality and credibility of the government's scientific information, with a focus on pre-dissemination procedures.
  - Highly influential scientific assessments require more rigorous review than other scientific information.
  - http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf

Historical Perspective (3)

- Bulletin on Agency Good Guidance Practices (2007)
  - Goal is to increase the quality, transparency, accountability, and coordination with respect to significant guidance documents.
  - http://www.whitehouse.gov/omb/inforeg/regpol.html#ggp

2006 Proposed Bulletin on Risk Assessment

- To improve the technical quality and transparency of agency risk assessments related to environment, health, and safety.

- Risk assessments are important tools for estimating the likelihood and severity of risks to human health, safety, and the environment and for informing decisions on how to manage those risks.

- Transparent and accurate risk assessments are necessary for agencies and other decision makers to make wise risk management decisions during the formation of agency rules and policy decisions.

- The proposed bulletin set minimum expectations but at the same time provided flexibility.

2006 Proposed Bulletin on Risk Assessment: History

- Released January 2006 as a proposal
- OMB requested a formal review from the National Academy of Sciences (NAS)
  - Review was equally funded by: EPA, HHS, USDA, DOD, DOL, DOE, and NASA
- NAS provided a formal report.
  - http://www.nap.edu/catalog.php?record_id=11811
- OMB had an extended public comment period and also conducted a rigorous interagency review.
  - Public Comments: http://www.whitehouse.gov/omb/inforeg/comments_rab/list_rab2006.html

2006 Proposed Bulletin on Risk Assessment: Results of NAS review

- While the NAS was supportive of the goal of "increasing the quality and objectivity of risk assessment in the federal government," the panel recommended an approach that would "outline goals and general principles."

- After reviewing the recommendations of the NAS, as well as feedback from interagency review and public comments, we decided to follow the NAS recommendation and did not issue the proposed bulletin in final form.

- Rather, we issued an Updated Principles of Risk Analysis Memorandum to reinforce generally accepted principles for risk analysis.

2007 Principles for Risk Analysis

2007 Principles for Risk Analysis: Introduction (1)

- In 1995 an interagency workgroup, co-chaired by OMB and OSTP developed principles for risk analysis related to environment health and safety.

- This 2007 memorandum, jointly released by OMB and OSTP reiterates the risk analysis principles released by OMB in 1995 and reinforces them with more recent guidance from the scientific community, Congress, and the Executive Branch.

- This memorandum is one aspect of larger OMB and OSTP efforts to improve the quality of the information which the federal government produces and relies on.

2007 Principles for Risk Analysis: Introduction (2)

- Following the principles in this memo will enhance the scientific quality, objectivity, and utility of Agency risk analyses and will also improve efficiency and consistency among the federal family.

- Agencies should already be following these 1995 principles, which this memorandum reinforces with references to more recent literature.

- While the Principles were aspirational in 1995, after nearly twelve years time, OMB and OSTP expect agencies to conduct risk analyses following the generally accepted principles presented in this memorandum.

2007 Principles for Risk Analysis: Introduction (3)

- This memorandum does not broaden or change the scope of the OMB Information Quality Guidelines, the Peer Review Bulletin, the Bulletin on Good Guidance, or OMB Circular A-4.

- Like the 1995 memo, the principles are divided into five parts:
  - General Principles
  - Principles for Risk Assessment
  - Principles for Risk Management
  - Principles for Risk Communication
  - Principles for Priority Setting.

2007 Principles for Risk Analysis: General Principles

2007 Principles for Risk Analysis: General Principles (1)

1. These Principles are intended to be goals for agency activities with respect to the assessment, management, and communication of environmental, health, and safety risks. Agencies should recognize that risk analysis is a tool—one of many, but nonetheless an important tool—in the regulatory tool kit. These Principles are intended to provide a general policy framework for evaluating and reducing risk, while recognizing that risk analysis is an evolving process and agencies must retain sufficient flexibility to incorporate scientific advances.

2. The Principles in this document are intended to be applied and interpreted in the context of statutory policies and requirements, and Administration priorities.

2007 Principles for Risk Analysis: General Principles (2)

3. As stated in Executive Order No. 12866, “ In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction” [Section 1(b)(4)]. Further, in developing regulations, federal agencies should consider “…how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency” [Section 4(c)(1)(D)].

2007 Principles for Risk Analysis: General Principles (3)

4. In undertaking risk analyses, agencies should establish and maintain a clear distinction between the identification, quantification, and characterization of risks, and the selection of methods or mechanisms for managing risks. Such a distinction, however, does not mean separation. Risk management policies may induce changes in human behaviors that can alter risks (i.e., reduce, increase, or change their character), and these linkages must be incorporated into evaluations of the effectiveness of such policies.

5. The depth or extent of the analysis of the risks, benefits and costs associated with a decision should be commensurate with the nature and significance of the decision.

2007 Principles for Risk Analysis: Principles for Risk Assessment

2007 Principles for Risk Analysis: Principles for Risk Assessment (1)

1. Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.

2. Characterizations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterizations should be broad enough to inform the range of policies to reduce risks.

3. Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.

2007 Principles for Risk Analysis: Principles for Risk Assessment (2)

4. Risk assessments should encompass all appropriate hazards (e.g., acute and chronic risks, including cancer and non-cancer risks, to human health and the environment). In addition to considering the full population at risk, attention should be directed to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed.

5. Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximize its use.

6. Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

2007 Principles for Risk Analysis: Principles for Risk Management

2007 Principles for Risk Analysis: Principles for Risk Management (1)

1. In making significant risk management decisions, agencies should analyze the distribution of the risks and the benefits and costs (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies, including regulation, positive and negative economic incentives, and other ways to encourage behavioral changes to reduce risks (e.g., information dissemination), should be evaluated. Agencies should employ the best available scientific, economic and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and methods of data development.

2007 Principles for Risk Analysis: Principles for Risk Management (2)

2. In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).

2007 Principles for Risk Analysis: Principles for Risk Communication

2007 Principles for Risk Analysis: Principles for Risk Communication (1)

1. Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and “experts” in relevant disciplines, and the public.

2007 Principles for Risk Analysis: Principles for Risk Communication (2)

2. Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner.

   To maximize public understanding and participation in risk-related decisions, agencies should:

   a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
   b. describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
   c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risk; and,
   d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

2007 Principles for Risk Analysis: Principles for Priority Setting

2007 Principles for Risk Analysis: Principles for Priority Setting (1)

1. To inform priority setting, agencies should seek to compare risks, grouping them in broad categories of concern (e.g., high, moderate, and low).

2. Agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first, accounting for relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.

2007 Principles for Risk Analysis: Principles for Priority Setting (2)

3. The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organizations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.

4. Agencies should attempt to coordinate risk reduction efforts wherever feasible and appropriate.

Questions?